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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,202	08/05/2003	Julio C. Spinelli	279.342US2	6793

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EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT PAPER NUMBER

3762

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/634,202	Applicant(s) SPINELLI ET AL.	
	Examiner <i>Carl H. Layno</i> Carl H. Layno <i>8/12/04</i>	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8-17 is/are allowed.
- 6) ☒ Claim(s) 1,2,7 and 18 is/are rejected.
- 7) ☒ Claim(s) 3-6,19 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/5/2003</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgement is made of applicant's claim for priority as a Continuation of U.S. Application Serial No.09/748,765, filed December 26, 2000, now U.S. Patent No.6,611,712.

### ***Information Disclosure Statement***

2. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449) which was received by the Office on August 8, 2003.

### ***Drawings***

3. Applicant's formal drawings were received by the Office on August 5, 2003 and have been approved by the Examiner.

### ***Specification***

4. The disclosure is objected to because of the following informalities:
  - p.1, lines 5-6, the first paragraph of the specification should be updated to reflect the fact that U.S. Patent Application Serial No. 09/748,765 is now U.S. Patent No.6,611,712, and
  - p.8, line 19, the reference to "Fig.1" should be changed to "Fig.3".Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

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5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Sholder '493.

The Sholder '493 patent describes an implantable pacemaker with capture verification circuits (Fig.1) including bipolar atrial and ventricular leads **32,38** (col.6, lines 13-22) having tip (**34,40**) and ring electrodes (**36,42**), respectively, acting as the cathode and anode electrodes. The pacemaker case **46** includes two electrodes **70,80** performing the function of applicant's reference electrode. Circuitry includes a pulse generator **54** and pulse output circuits **56** for outputting stimulus pulses to both bipolar leads. The Sholder '493 device includes capture sense amplifier circuits for measuring unipolar capture threshold. Applicant's attention is directed to col.3, lines 58-62, which states that "in a bipolar system, the pacing system may pace in a bipolar configuration between the tip and the ring of the pacing lead(s), and sense capture between the tip... of the pacing lead(s) and the indifferent electrode". In addition, applicant's attention is also directed to col.8, lines 57-66.

In regard to claim 2, indifferent reference electrode **80** is attached to the housing of the pacemaker case **46**. See Fig.1.

In regard to claim 18, the Sholder device delivers pacing pulses in a bipolar fashion using bipolar leads but senses in a unipolar fashion using tip (cathode) and indifferent (reference) electrodes (col.3, lines 58-62). Stimulation amplitudes may vary automatically depending upon

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sensed capture thresholds (col.4, lines 3-9). Specifically, the stimulation pulse energy will have an amplitude slightly above the lowest pulse amplitude which caused capture.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sholder '493 in view of Hemming et al '512.

Though the Sholder '493 patent describes many of applicant's claimed device features it fails to specify which electrodes are the cathode and anode.

The Hemming et al '512 patent describes an implantable pacemaker having endocardial pacing lead **14** (Fig.1) whose tip electrode **50** (Fig.5a) is defined as a cathode and whose ring electrode **52** (Fig.5a) is defined as an anode.

To have specified the tip and ring electrodes of the Sholder ventricular pacing lead as being the cathode and anode, respectively, would have been obvious to one of ordinary skill in the art in view of the teachings of Hemming et al, which shows that this configuration is well known in the art.

***Allowable Subject Matter***

9. Claims 3-6, 19, and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 8-17 are allowed.

11. The following is a statement of reasons for the indication of allowable subject matter:

Independent claim 8 describes details of a cardiac rhythm management device similar to that of claim 1 but further specifying a “means for measuring a unipolar capture threshold...to determine which of the proximal and distal electrodes should be used as an anode and cathode for bipolar stimulation”. The prior art references of record fail to show or teach the capability of determining anode/cathode selection based upon measured unipolar thresholds. As a result, the Examiner deems this claim and its depending claims to be allowable.

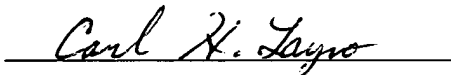
Similarly, independent claim 13 recites method steps corresponding to the device of claim 8 including the unique step of: ”selecting the electrode of the bipolar lead having the lowest unipolar capture threshold as the cathode for bipolar stimulation, with the other electrode serving as the anode”. Again, the Examiner was unable to find references in the prior art showing or teaching this step; consequently, the Examiner also deems this claim and its depending claims to be allowable.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message ([carl.layno@uspto.gov](mailto:carl.layno@uspto.gov)) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. All faxed communications should be sent to the Office's new official FAX number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.

  
CARL LAYNO  
PRIMARY EXAMINER

CHL  
8/11/2004